K053350

JAN 19 2006

SECTION 11 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

A. Submitter Information

Submitter's name:	Codman & Shurtleff, Inc.
Address:	325 Paramount Drive Raynham, MA 02767
Telephone:	508-828-3571
Fax:	508-828-2777
Contact Person:	Brian A. Kanerviko
Date of Submission:	December 1, 2005

B. Trade/Device Name: Codman Hakim Shunt Systems.
Common Name: Shunt
Classification Name: Central Nervous System Fluid Shunt and Components
Regulation Number: 882.550

C. Predicate Device: Codman Hakim Shunt Systems (K020667).
Codman Hakim Programmable Valve (K974739)
Codman Hakim Precision Valve (K944222)

D. Device Description: The Codman Hakim Shunt System incorporates all the possible shunt system features commercially available in the Codman Hakim line of products. The proposed device is adding a dimensional modification to the predicate valves listed above that are part of the Codman Hakim Shunt System.

E. Intended Use: Codman Hakim Shunt Systems are implantable devices that provide constant intraventricular pressure and drainage of cerebrospinal fluid for the management of hydrocephalus.

Codman Hakim Shunt Systems are available with or without CODMAN BACTISEAL Catheters, which are intended for use in the treatment of hydrocephalus as a component of a shunt system when draining or shunting of cerebrospinal fluid is indicated.

Codman Hakim Shunt Systems are also available with or without SIPHONGUARD. The SIPHONGUARD device is designed to reduce the potential hazards of excessive lowering of intraventricular pressure (with respect to atmospheric pressure) when a patient is in an upright position.

F. Summary of technological characteristics of the proposed to the predicate device.

The technological characteristics of the proposed device are the exact same as the predicate device.

G. Performance Data

Bench testing has been completed and supports the safety and effectiveness of the proposed device for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 19 2006

Mr. Brian A. Kanerviko
Senior Regulatory Affairs Specialist
Codman & Shurtleff, Inc.
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K053350
Trade/Device Name: Codman Hakim Shunt Systems
Regulation Number: 21 CFR 882.5550
Regulation Name: Central nervous system fluid shunt and components
Regulatory Class: II
Product Code: JXG
Dated: December 22, 2005
Received: December 23, 2005

Dear Mr. Kanerviko:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Buchman
for

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):K053350

Device Name: Codman Hakim Shunt Systems: Addition of a silicone platform to the base of the Codman Hakim Programmable and Precision Valve

Indications For Use:
Codman Hakim Shunt Systems are implantable devices that provide constant intraventricular pressure and drainage of cerebrospinal fluid for the management of hydrocephalus.

Codman Hakim Shunt Systems are available with or without CODMAN BACTISEAL Catheters, which are intended for use in the treatment of hydrocephalus as a component of a shunt system when draining or shunting of cerebrospinal fluid is indicated.

Codman Hakim Shunt Systems are also available with or without SIPHONGUARD. The SIPHONGUARD device is designed to reduce the potential hazards of excessive lowering of intraventricular pressure (with respect to atmospheric pressure) when a patient is in an upright position.

Prescription Use ____x___ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bruelhart for MXM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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